

Department of Energy

Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221
July 8, 2003



Dr. Amrit S. Boparai Analytical Chemistry Laboratory Argonne National Laboratory-East 9700 South Cass Avenue Argonne, IL 60439-4837

RE:

Issuance of Argonne National Laboratory-East (ANL-E) CARs 03-065 through 03-068 for Audit A-03-18

Dear Dr. Boparai:

The Carlsbad Field Office (CBFO) performed Audit A-03-18 of Argonne national Laboratory-East, on June 24 and 25, 2003. The scope of this audit was the adequacy, implementation, and effectiveness of the quality assurance elements and technical elements related to the procedures and processes used by ANL-E in it's role as the sample preparation contractor for the Headspace Gas Performance Demonstration Program. As a result of this audit, the subject CARs have been issued.

Please determine and document on the enclosed CAR continuation sheets your proposed corrective action plans for the CARs. Please forward the proposed corrective action plans and schedules for completion to me prior to the response due dates identified in CAR block 14.

If you have any questions or comments, please contact me at (505) 234-7442.

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M. Lea Chism

Quality Assurance Specialist

Enclosure

cc: w/enclosure A. Holland, CBFO *ED K. Watson, CBFO *ED M. Brown, CBFO *ED K. Joshi, DOE-CH *ED A Gabel, DOE-CH *ED M. Eagle, EPA *ED S. Zappe, NMED *ED B. Walker, EEG *ED A. Arceo, CTAC *ED C. Watkins, CTAC *ED D. Gill, CTAC *ED T. Bowden, CTAC *ED K. Dunbar, WTS CBFO QA File CBFO M&RC

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1. CAR No.: 03-065	2. Activity Report No.:	A-03-18	3. Page 1 of
4. Controlling Document: SW-846, Metho Organic Compounds By Gas Chromatograph (GC/MS), Rev. 2	d 8260B Volatile y/Mass Spectrometry	5. CBFO Assessmen	t Team Leader: Lea Chism
6. Responsible Organization: ; ANL-E CM	T ACL	7. CAQ Was Discuss	sed With: A. Boparai, M. Kalensky
8. Requirement that was violated: SW-846 should be prepared at a minimum of five different and 5.8) or from a premixed certified solution	erent concentrations from t	Section 5.12.1, states, in the secondary dilution of	part: "Initial calibration standards f stock standards (see Sections 5.7
9. Condition Adverse to Quality: The stand manufacturer's expiration date. For example standards on 2/18/03.	lards used for preparation of ALM030407 and ALM02	of calibration standards 3835 expired in 2001 b	are used beyond their ut were used to make calibration
10. Suggested Actions (Optional):		estation (the contraction of the	мін в урання поміна в к ост <mark>одинецино</mark> вано со стой <u>подпечення в до за подпечення в до за подпечення в до за до</u>
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13. CAR Initiator: Dorothy Gill	COCCUMATION CONTROL SERVICE CONTROL CO	Date:	
14. Response Due Date: 08-08- Required Corrective Action Completic 15. a.Concurrence: N. Lea U.	A. Harris and A.	ve Action Plan Requir	ed: (VES)NO
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c. NA Quality Assurance Ma	nager Date	and the second s	
16. Corrective Actions Proposed by the Re	sponsible Organization:	Use CAR Continuatio	n Sheet
17. Acceptance of Proposed Corrective Act	***************************************		
Assessment Team Leader	Date		
18. Verification of Corrective Action Comp	oletion: (Use CAR Contin	uation Sheet)	
19a. Verified By: Name	And the state of t	Date	
19b. Trend Cause Code:			
20. Closure:			4 (5.5)

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1. CAR No.: 03-066	2. Activity Report No.:	A-03-18	3. Page 1 of 2	
4. Controlling Document: SW-846, Method Organic Compounds By Gas Chromatograph (GC/MS), Rev. 2 and Method 8000B Determ Separations, WAP, and QAPD	v/Mass Spectrometry	5. CBFO As	essment Team Leader: Lea Chism	
6. Responsible Organization: : ANL-E CM	TACL	7. CAQ Was	Discussed With: A. Boparai, M. Kale	nsky
8. Requirement that was violated: (See Co	ontinuation Sheet)		мен и мариального в достивно в неводения в неводения в неводения в неводения в неводения в неводения в неводен	**************************************
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11b. Work Suspension Recommended	(Yes or No):X			
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15. a. Concurrence: M. Lea Chis Assessment Team Leader	$m = \frac{07/08/03}{\text{Date}}$	bL.f Respons	Die Assistant Manager Date	
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Block # 8 Requirement that was violated:

A.SW-846, Method 8260B, Volatile Organic Compounds By Gas Chromatography/Mass Spectrometry (GC/MS), Rev. 2, Section 7.6.1, states, "The qualitative identification of each compound determined by this method is based on retention time, and on comparison of the sample mass spectrum, after background correction, with characteristic ions in a reference mass spectrum. The reference mass spectrum must be generated by the laboratory using the conditions of this method. The characteristic ions from the reference mass spectrum are defined to be the three ions of greatest relative intensity, or any ions over 30% relative intensity if less than three such ions occur in the reference spectrum." Method 8000B, Determinative Chromatographic Separations Section 7.6.1, states, "Before establishing retention time windows, make sure that the chromatographic system is operating reliably and that the system conditions have been optimized for the target analytes and surrogates in the sample matrix to be analyzed."

- B. WAP, Table B 3-3 Summary of Laboratory Quality Control Samples and Frequencies for Gas Volatile Organic Compound Analysis, Method Performance Samples must meet method QAOs (WAP Table B3-2 provides methods QAOs for accuracy and precision).
- C. QAPD, Rev. 5, Section 2.1.2.8, states "Methods for demonstrating that the work was performed as required (such as provisions for recording inspection and test results, check-off lists, or sign-off blocks), and Section 2.1.2.9. Identification and classification of QA records to be generated by the implementing procedure
- D. WAP, Table B1-1, Gas Sample Requirements, Holding Temperatures 0-40°C

Block #9 Condition Adverse to Quality:

Adequacy issue: Procedure ACL-168, Rev. 5, does not address the following:

- A. The initial calibration section (8.4.1) does not describe how retention time and retention time windows are determined.
- B. The procedure does not require generation of method precision and accuracy data.
- C. The procedure does not describe what records are generated by this procedure, nor how these records are dispositioned.
- D. The procedure does not address the holding temperature requirement for VOCs SUMMA canister, hence there was no documentation for monitoring the temperature in the area for storage of PDP and calibration canisters.

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1. CAR No.: 03-067	2. Activity Report No.:	A-03-18	3. Page 1 of 2
4. Controlling Document: SOP ACL-211, I	Revision 4	5. CBFO Assessmen	nt Team Leader: Lea Chism
6. Responsible Organization: ANL-E CMT	CACL	7. CAQ Was Discus	sed With: Mike Kalonsky
8. Requirement that was violated: A) SOP ACL-211, Section 4.6.1 states, "In a and content of all canisters used in the HSGB) SOP ACL-211, Section 3, Receipt Inspectional verify that the compounds listed on the their concentrations are approximately the solution (or initialing) and dating the certificate of a	PDP." ction states, "Upon receipt to certificate of analysis at same as ordered. The veri	of the HSGPDP gas c tached to each cylinde fication shall be docu	ylinders from the vendor, the ACL are the same as ordered and that
 Condition Adverse to Quality: A) There is no record of all canisters used in scrialized notebook. The canisters not being: B) There is no documentation of receipt inspecylinder are the same as ordered and that their ANL" are not present on any of the certificate 	used in the most recent cyc ection to verify that the cor r concentrations are approx	le are not accounted fo npounds listed on the c imately the same as or	r in ACL documentation, ertificate of analysis attached to each dered. The words "received by
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4. Controlling Document: SOP ACL-158,	controlling Document: SOP ACL-158, Rev. 4		5. CBFO Assessment Team Leader: Lea Chism	
6. Responsible Organization: ANL-E CMT ACL		7. CAQ Was Discussed With; Mike Kalensky		
8. Requirement that was violated: SOP At Bourdon type pressure gauge: 0 to 345 kPa and Flumidiffer: 300 mL stainless steel cylinder approvide moisture to the zero air supply. Dry a reservoir."	(0 to 50 psig) to monitor ze containing high performance	ro air pressure. c liquid chromatograph	y (HPLC) grade defonized water to	
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10. Suggested Actions (Optional):	у сентвення для предержения с то у предвенення то для у доворого до до доворого до до доворого до до доворого д	одовогового у ученовання (5% газання выбольно и ученовання выпольной выпольной выпольной выпольной выпольной в -	erregues and the second control of the secon	
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